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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,044	07/21/1998	CONCEICAO MINETTI	3842-4036US2	1759

7590 08/22/2003

MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/22/2003

43

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/120,044

Applicant(s)

Minetti et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Aug 6, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY (check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Aug 6, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 43-51
- Claim(s) objected to: _____
- Claim(s) rejected: 35-37, 42, 53, and 60-80
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Aug. 03
S. DEVI, PH.D.
PRIMARY EXAMINER
ART UNIT 1645

ATTACHMENT TO ADVISORY ACTION

The new limitations added to claim 35: '61, 148 and 195, *and* more than one amino acid substitution

wherein said modified pneumolysin 'polypeptide having *one or* more than one amino acid substitution' was not presented previously and change the scope of the claims raising new issues that require further consideration under 35 U.S.C. § 112 [Emphasis added].

The new limitations added to claim 80: '61, 148 and 195, *and* more than one amino acid substitutions

wherein said modified pneumolysin 'having *one or* more amino acid substitutions' was not presented previously and raise new issues that require further consideration under 35 U.S.C. § 112 [Emphasis added].

The new limitations added to the base claim 35 change the scope of the claim and now require the modified pneumolysin to have one amino acid substitution at position 61, 148 or 195 **plus** 'more than one' (i.e., at least two) amino acid substitutions at the specifically recited positions. This renders the scope of dependent claims 65-68 indefinite and indeterminate, which claims, as amended, contain the confusing and/or inconsistent limitation 'said one amino acid substitution', thus raising new issues that require further consideration under 35 U.S.C. § 112.

The status of claims 16-21 and 27-30, now indicated as '(withdrawn)', is incorrect, because these claims were canceled via the preliminary amendment filed 12/21/00 (paper no. 27).

August, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER